

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CLASSEN, John Barthelme

Serial No.: 09/660,584

Filed: September 12, 2000

For: METHOD AND COMPOSITION
FOR AN EARLY VACCINE...

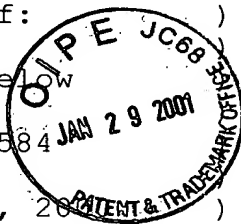
Art Unit: 1642

Examiner:

Washington, D.C.

January 29, 2001

Docket No.: CLASSEN=1D



Pre Amt B/#6
4.29.02
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PRELIMINARY AMENDMENT

Honorable Commissioner of Patents
Washington, D.C. 20231

S i r :

Prior to further action, please enter the following
amendments and remarks:

IN THE CLAIMS

Please amend claim 97 as follows:

97 (amended). A method of [determining] predicting whether
a vaccine, or an immunization schedule, affects the incidence,
prevalence or frequency of a chronic immune-mediated disorder in
humans, [in a treatment group of mammals, relative to a control
group of mammals,] which comprises immunizing mammals in [the]
a treatment group of mammals with a vaccine comprising one or
more immunogens, or with one or more doses of one or more
immunogens, according to said immunization schedule, and
comparing the incidence, prevalence or frequency of said chronic
immune-mediated disorder, in [the] treatment group, with that in
[the] a control group of mammals,

wherein said chronic immune mediated disorder is a diabetes
mellitus which has not been chemically induced by
streptozotocin,

wherein said immunogen is one other than a BCG immunogen,
wherein the mammal is an animal model for human diabetes, and
where the vaccines administered to the control group and the
treatment group, or the immunization schedules according to which